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## PERFORMANCE WORK STATEMENT CONTRACT NO.

TITLE: Project Management Support for NCEA

Specify Section & Paragraph SOW: A. Assessment Issues and Documents and G. Project Management

**PERIOD of PERFORMANCE:** June 2019 – June 2020

## I. PURPOSE

The purpose of this Task Order is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA) including support for both program management as well as individual project management activities related to assessment or technical work product development and production practices. The goal is to address cross-cutting assessment and organizational issues that impact the development of NCEA work products. Results will include implementation of improved process methods and/or tools designed to track and facilitate an increase in the pace of development of multiple ongoing work within NCEA.

#### II. BACKGROUND

The National Center for Environmental Assessment (NCEA), a major component of EPA's Office of Research and Development (ORD), with headquarters in Washington, DC, is EPA's national resource center for human health and ecological risk assessment. NCEA occupies a critical position in ORD between researchers in other parts of ORD and outside of EPA who are generating new findings and data, and the regulators in EPA's program offices and regions who must make regulatory, enforcement, and remedial action decisions. NCEA prepares technical reports and assessments that integrate and evaluate the most up-to-date research and serve as major elements of the science foundation supporting EPA policies. As a result, NCEA plays an important role as a consultant to EPA programs and regions on the use of science in environmental decision making and also influences the direction of environmental research.

#### III. STATEMENT OF WORK

This task order will provide program and project management technical and administrative support to NCEA in order to facilitate tracking, management and production of multiple ongoing work products within the center's various research programs.

## **Task 1: Establish Communication**

Within 3 days of the start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and other EPA staff and any appropriate contractor staff to clarify outstanding questions and confirm the schedule of specific tasks. Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the Project Officer.

#### Task 2: Work Plan and Staffing Plan

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The

Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that lists assigned personnel by task and the qualifications of the proposed personnel.

Deliverables: Technical Work Plan and Staffing Plan

# Task 3: Planning and Implementation of Methods to Improve Program Management Activities within NCEA

Consistent with PMI Project/Program Management guidelines and best practices, work with NCEA staff to assess program management activities of various programs within NCEA. This task will include the following subtasks:

**Subtask 3.1:** Assist with further implementation of Program Management tools and techniques within the IRIS Program. Work with NCEA staff to further develop best practices for promoting communication and operations. Provide onsite support by assisting with development of management guidelines, communicating/training activities with IRIS Program staff, supporting development of resource management planning, and other efforts that will assist with the efficient operation of the IRIS Program.

**Deliverables:** Guidance materials, training activities, tools for resource management. Timeline to be determined.

**Subtask 3.2:** Assist with assessing the status of Program Management activities within the PPRTV program (mostly managed through the Cincinnati, Ohio office of NCEA). Provide a report of the current status of program management along with recommendations for improvements, guidance materials, or other best practices.

**Deliverables:** Assessment report of the status of Program Management of the Provisional Peer Reviewed Toxicity Value (PPRTV) Program and recommended improvements. Timeline should be within the first 2 months of the PoP.

**Subtask 3.3:** Implement recommendations for program management of the PPRTV Program. Work with NCEA staff to do a phased approach of agreed-upon recommendations for improving and assisting program management of the PPRTV Program. A portion of this effort shall be done in-person at the Cincinnati, Ohio office.

**Deliverables:** Guidance materials, training activities, tools for resource management or other best practices. Timeline to be determined.

**Subtasks 3.4:** Begin to assess other programs within NCEA for initial recommendations for program management. Examples might include the ISA Program in RTP or the Global Program in Washington DC.

**Deliverables:** Short summaries and schedule for assessing these other programs within NCEA. Timeline to be determined, but after the PPRTV Program assessment is complete.

# <u>Task 4: Planning and Implementation of Methods to Improve Project Management Activities within NCEA</u>

Consistent with PMI Project/Program Management guidelines and best practices, work with NCEA staff to assess and participate in project management activities of various programs within NCEA. This task will include the following subtasks:

Subtask 4.1: Assist with Project Management efforts of the IRIS Program by

- Providing support for staged implementation of new and/or modified methods or approaches for continued improvement in assessment coordination and development activities. Working towards incorporating all active or new IRIS projects in the project management system.
- Continuing to develop or provide tools that will assist in implementation of project management activities and provide training to support implementation of these tools including MS Project Online.
- Continuing to assist in developing reporting or tracking processes and providing training to support implementation of new processes.
- Identifying, tracking, and analyzing metrics to measure progress towards goals, as changes are implemented at the project level.
- Working directly with assessment team staff to develop and maintain assessment tracking and reporting measures. Assist with facilitating meetings and schedules.

**Deliverables:** Summaries of progress, meeting minutes, decision documentation, assessment tracking documentation.

### Subtask 4.2: Assist with Project Management efforts of the PPRTV Program by

- Providing support for staged implementation of new and/or modified methods or approaches for continued improvement in assessment coordination and development activities. Working towards incorporating all active or new projects in the project management system.
- Developing/providing tools that will assist in implementation of project management activities and provide training to support implementation of these tools including MS Project Online.
- Assisting in developing reporting or tracking processes and providing training to support implementation of new processes.
- Identifying, tracking, and analyzing metrics to measure progress towards goals, as changes are implemented at the project level.
- Working directly with assessment team staff to develop and maintain assessment tracking and reporting measures. Assist with facilitating meetings and schedules.
- A portion of this work shall be done in-person at the Cincinnati, Ohio office.

**Deliverables:** Summaries of progress, meeting minutes, decision documentation, assessment tracking documentation. Timeline to begin after program management assessment is complete.

## Subtask 4.3: Assist with Project Management efforts for other NCEA Programs by

- Providing support for staged implementation of new and/or modified methods or approaches for continued improvement in assessment coordination and development activities. Working towards incorporating all active or new projects in the project management system.
- Developing/providing tools that will assist in implementation of project management activities and provide training to support implementation of these tools including MS Project Online.
- Assisting in developing reporting or tracking processes and providing training to support implementation of new processes.
- Identifying, tracking, and analyzing metrics to measure progress towards goals, as changes are implemented at the project level.
- Working directly with assessment team staff to develop and maintain assessment tracking and reporting measures. Assist with facilitating meetings and schedules.

**Deliverables:** Summaries of progress, meeting minutes, decision documentation, assessment tracking documentation. Timeline to be determined.

## Task 5: Assist in Implementing Project/Program Management System

Assist in standing up a project/program management system to be used at both the product level and the program level. Provide training and support to staff in use. Assist in developing functionality for use by staff and management.

Assist in developing visualization reports for both project management as well as scientific work products. Reports/dashboards/visualizations should be developed in a visualization tool (e.g., MS Excel or Power BI or other appropriate tool) and should be able to be distributed to the appropriate user group (e.g., SharePoint).

Continue to assist in developing Standard Operating Procedures and training guides for use by the IRIS Program and IRIS staff.

**Deliverables**: Project/program management system and reporting system. SOPs and/or training guides as requested. Other visualizations as requested. Timeline to be determined.

In order to accomplish the activities of this Task Order, the Contractor will have staff members participate inperson in the Washington D.C. NCEA offices with additional support as needed through offsite personnel. Contractor staff working on project management should have PMP certification (Project Management Professional) certification and it would be helpful to have a science background. They should also have expertise in MS Project and MS Project Online. Staff assigned to visualization tools should be familiar with PowerBI, Qlik Sense, MS Excel or other data visualization software packages.

For planning purposes, the Contractor PMP should plan on travel to the Cincinnati, Ohio office for two onsite visits to meet with staff and managers. Travel duration shall be for two days each and planning should include an overnight stay.

#### IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel, Word, PDFs, InDesign, SharePoint, MS Project, Power BI).

### V. DELIVERABLES AND SCHEDULE

Task 1: Establish communication	3 days after award of WA and to schedule set
Task 2: Work plan/Staffing plan	15 days after award
Task 3: Program Management	Reports weekly
Task 4: Project Management	Reports weekly
Task 5: Data visualization	Reports weekly

#### VI. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
- 2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

### VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the program officer (PO), or the contracting officer (CO).

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA.

### VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the WAM at the initiation of the work assignment. Standard reporting requirements of the contract apply for active/completed projects.

#### IX. OTHER REQUIREMENTS

The TOPO will have oversight on all materials developed by the contractor. The primary communication mechanism between the TOPO and the contractor shall be email.

In cases where the work to be performed is of a highly scientific or technical nature or requires consultation or interactions, it may be more expedient for the contractor to interact directly with members of the scientific/technical staff.

## X. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this task order shall be sent to the PO.

#### **Task Order Manager:**

Vicki Soto U.S. EPA/ORD/NCEA MC 8601-P 1200 Pennsylvania Ave. NW Washington, DC 20460 soto.vicki@epa.gov (202) 564-3077

## **Alternate Task Order Manager:**

James Avery
U.S. EPA/ORD/NCEA
MC 8601-P
1200 Pennsylvania Ave. NW
Washington, DC 20460
avery.james@epa.gov
(202) 564-1494

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	109 TW Alexander Drive				
	www2.epa.gov/financial/contracts				
	Durham NC 27711				
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(Signature of person authorized to sign)				(Signature of Contracting Officer)		

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	US Environmental Protection Agency				
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	CHANGES FOR LINE ITEM NUMBER: 1				
	Total Amount changed				
	from \$700,993.00 to \$1,020,336.00				
	Obligated Amount for this Modification:				
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	End Date changed from 30-SEP-20 to 31-MAR-21				
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	Amount changed from \$700,993.00 to \$1,020,336.00				
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	NEW ACCOUNTING CODE ADDED:				
	Account code:				
	19-20-C-26D1000-000F84-2532-26A5C-2026D1C020-004				
	Beginning FiscalYear 19				
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	Fund (Appropriation) C				
	Budget Organization 26D1000				
	Program (PRC) 000F84				
	Budget (BOC) 2532				
	Job # (Site/Project)				
	Cost Organization 26A5C				
	DCN-LineID 2026D1C020-004				
	Quantity: 0				
	Amount: \$12,526.00				
	NEW ACCOUNTING CODE ADDED:				
	Account code:				
	19-20-C3-26D1000-000F84-2532-26A5C-2026D1C020-003				
	Beginning FiscalYear 19				
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	Fund (Appropriation) C3				
	Budget Organization 26D1000				
	Program (PRC) 000F84				
	Budget (BOC) 2532				
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	20-21-C-26D1000-000F84-2532-26A5C-2026D1C020-002				
	Beginning FiscalYear 20				
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	Fund (Appropriation) C				
	Budget Organization 26D1000				
	Program (PRC) 000F84				
	Budget (BOC) 2532				
	Job # (Site/Project)				
	Cost Organization 26A5C				
	DCN-LineID 2026D1C020-002				
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	Amount: \$285,953.00				
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# ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION

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68HERC19F0213 07/02/2019 ITEM NO. SUPPLIES/SERVICES QUANTITY UNIT UNIT AMOUNT QUANTITY ORDERED PRICE ACCEPTED (d) (a) (b) (c) (e) (g) Admin Office: CPOD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: NWD Cincinnati OH 45268 Accounting Info: 19-20-B-69A-000CD7-2505-TLRHZQB-1969AC9014-0 01 BFY: 19 EFY: 20 Fund: B Budget Org: 69A Program (PRC): 000CD7 Budget (BOC): 2505 Cost: TLRHZQB DCN - Line ID: 1969AC9014-001 Period of Performance: 07/02/2019 to 07/01/2020 0001 Contract 68HERC19D0003 TO-0007 Lead (Pb) 193,534.00 Regulatory Analysis Support Activities

\$193,534.00

## PERFORMANCE WORK STATEMENT HHRA Contract 68HERC19D0003 Task Order 68HERC19F0213

## **TITLE:** Lead (Pb) Regulatory Analysis Support Activities

**Specify Section & Paragraph SOW: Please select from the following:** D. Analysis, Document & Issue Paper Preparation, E. Risk Assessment Support, G. Literature Search

PERIOD OF PERFORMANCE: CO award to 12 months

#### I. PURPOSE

The primary purpose of this task order (TO) is to provide continued services to the U.S. Environmental Protection Agency's (EPA) (hereinafter EPA or Agency) Office of Pollution Prevention and Toxics (OPPT), in the completion of the analyses that support lead regulatory efforts for the following projects:

- Public and Commercial Buildings (P&CB)
- Lead Hazard Standard
- Lead Clearance Standard

A secondary purpose of this TO is to provide supplemental exposure support to OPPT for the following projects:

- Development or refinement of any model or approach, including documentation, developed for lead that also could be used to support assessment or other chemical substances of interest to OPPT
- Targeted support for components of exposure assessment for existing chemicals other than lead.

## II. BACKGROUND

EPA is undertaking rulemakings intended to revise certain provisions of TSCA related to implementation of the Lead (Pb) Program. Under previous contract EP-C-14-001, the contractor provided support for many activities including the following:

- Developing an approach for estimating the residential dust hazard standards that would achieve each of four alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change in children under age 6 associated with each alternative. This was reviewed by the Science Advisory Board SAB in July 2010
- Refining the approach for estimating the residential dust hazard standards that would achieve each of the three alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change associated with each alternative. The contractor estimated blood lead concentrations in children under age 6 using methods based on specific epidemiology papers.
- Developing an approach for estimating the dust hazard standards for interior renovations in P&CBs that would achieve each of three alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change in children under age 6 associated with each alternative dust hazard standard. The contractor developed an approach for estimating certain cardiovascular effects in adults for each alternative dust hazard standard.
- Refining the approach for estimating hazard standards in residences and P&CBs after a second review by the <u>SAB</u> in December 2010.

- Development of an Approach to estimate benefits from exterior renovations of P&CBs that contain lead paint. Blood lead estimates were estimated using the IEUBK model and IQ changes were estimated for young children. This Approach document was completed in 2012 but was not released because of a settlement agreement which combined exterior and interior renovations for P&CBs.
- Development of an Approach to estimate benefits from exterior and interior renovations of P&CBs that contain lead-based paint. Blood and bone lead estimates were estimated using an updated version of the Leggett model and IQ changes were estimated for children 0-10 while cardiovascular disease mortality, reduced kidney function, and low birth weight health outcomes were estimated for adults. This <a href="Approach">Approach</a> document was completed and released on August 6, 2014.
- The Approach document was then peer reviewed and a <u>peer review report</u> was received on February 27, 2015.
- Development of a Technical Support Document to support a Proposed Dust-Lead Hazard Standard rulemaking. This rule is expected to be finalized in June 2019.

#### III. STATEMENT OF WORK

#### **Task 1: Establish Communication**

Within 3 days of start date of this TO, the Contractor shall schedule a conference call (not to exceed 1 hour) with the COR and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

## Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the TO, that shows assigned personnel by task and the qualifications of the proposed personnel. This TO will require contractor staff to be thoroughly familiar with the exposures from lead dust and other media, blood lead modeling, and concentration response equations for IQ and other health effects. Contractor staff with expertise in pharmacokinetic modeling of lead, biostatistics for lead, and computer modeling for lead are essential for this TO.

The Contractor shall develop a QAPP for approval by the COR and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs (QAPP)"; "EPA Requirements for Quality Assurance Project Plans (QA/R-5)"; and "Appendix A. Guidance on Quality Assurance Project Plans for Secondary Research Data."

The contractor shall submit the QAPP simultaneously with the Work Plan for approval. The Contractor shall not perform any work involving environmental data for subsequent tasks under this TO until the Work Plan and QAPP are reviewed and approved. The contractor shall not perform any computer modeling work under this TO until the quality assurance statement is reviewed and approved by the COR and the OPPT QA Manager. Scoping work that plans how future work involving environmental data could occur as well as answering clarifying questions regarding already completed work involving environmental data may begin after the approval of the work plan.

# Task 3: Complete Exposure and Health Analyses for Ongoing Lead Regulatory Projects Task 3a: Public and Commercial Buildings Documentation

The contractor shall complete updates to the Approach document to be called: "Approach taken to Estimate Exposures and Incremental Health Effects from Lead due to Renovation, Repair, and Painting Activities in Public and Commercial Buildings." The document and its supplementary files shall document changes from the August 2014 Approach and provide response to peer review. Delivery of the Approach Document and its supplemental files is expected to be iterative with drafts submitted monthly. The final report is anticipated to have 10 chapters within the Approach document and 6 supplemental files. The contractor shall document versions carefully, incorporate comments from EPA, to determine when a chapter and/or supplemental file moves from draft to final status. Note, finalization of the "results" chapter is contingent upon finishing task 3b.

#### Task 3b: Public and Commercial Buildings Modeling

All model inputs have been refined and revised in previous option years except for model inputs dependent upon results of industry surveys. Within the option period, EPA expects results (including analysis and summary report from another contractor) to become available. The last step of the public and commercial buildings analysis will be to update model inputs, as needed, based on survey feedback, refine scenarios, and rerun the deterministic and Monte Carlo model so that those results can be incorporated into the results chapter under 3a.

## Task 3c: Finalize Lead (Pb) Dust Hazard Standard Approach Documentation

The contractor shall complete updates to the Approach document: "Technical Support Document: for Residential Dust-Lead Hazard Standards." This report refined information from the 2010 and 2011 Hazard Standard documents, peer review feedback, and consolidate into one updated document incorporated results of the literature search conducted under contract EP-C-14-001.

The contractor shall complete targeted updates to the report including documentation of references, responses to follow-up questions, and targeted editing prior to expected publication of the document in June 2020.

#### Task 3d: Update Lead (Pb) Dust Hazard Standard Modeling

The contractor shall respond to targeted questions regarding how modeling estimates were estimated. Multiple approaches were used to derive blood lead and IQ estimates and the contractor shall be prepared to summarize all approaches and respond to targeted questions about how input and output values were derived. The contractor shall maintain records of all files used for Dust-Lead Hazard Standard modeling and provide files to EPA through FTP link and/or posting to SharePoint.

#### Task 3e: Finalize Lead (Pb) Dust Hazard Clearance Approach Documentation

This document will include a conceptual model and analysis plan. The contractor will work collaboratively with the EPA COR and other EPA workgroup members (economists, rule-writers) to complete the conceptual model and analysis plan. The conceptual model and analysis plan should identify what is similar and different from the Technical Support Document for the hazard standard. Once completed and approved by EPA COR, the contractor shall implement the analysis plan. Likely components of the analysis plan are a quantitative and/or qualitative analysis of dust-lead exposures over time and their impact of blood lead levels and IQ change.

#### Task 3f: Update Lead (Pb) Dust Clearance Standard Modeling

The contractor shall complete modeling associated with linking exposed populations affected by a change in the dust lead clearance standard. Children exposed to elevated dust lead levels will have subsequent changes in their blood lead and IQ. These changes are required for regulatory analysis.

## Task 4: Develop, update, or refine Exposure Models or Databases used for Lead and applicable for other chemicals

Under previous contract EP-C-14-001, the contractor has developed a wide range of exposure models that could be further repurposed and used with chemicals other than lead. Examples of models developed to support Lead regulations include the Fortran version of the All-Ages Lead Model (AALM), applications of AERMOD for deposition, a soil and hard surface model, and an Indoor Dust Model. Examples of databases include generic building layouts for different building categories, monitoring and biomonitoring data, blood lead data, and data related to lead-safe work practices.

Task 4A: The contractor shall, upon receipt of technical direction, further develop stand-alone graphical user-interfaces and user guides which explain the calculations and defaults used in exposure model documentation through user guides. No more than two GUIs would be requested in the option year and EPA will follow up with technical direction prior to initiation of model development.

Task 4B: The contractor shall use blood lead modeling expertise to integrate, document, and finalize technical supporting documents for the AALM. The contractor shall support work leading up to the upcoming SAB review. The contractor shall plan to attend the SAB meeting. The contractor may help prepare materials for the SAB meeting including case-studies, examples, or applications of how the AALM could be applied. This may also include targeted calibrations that compare empirical data sets identified by EPA with modeled estimates. These data sets should include exposure estimate and blood lead values, ideally at multiple time points.

### IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [\*.(d), \*.out, \*opt, \*.ssn]).

#### V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of TO
Task 2. Staffing Plan, and QAPP	15 days after award
Task 3a: Public and Commercial Buildings Report	Monthly deliverables starting end
	of August until complete
Task 3b: Public and Commercial Buildings Modeling	Monthly deliverables starting end
	of August until complete
Task 3c: Hazard Standard Report	Weekly deliverables after
	workplan approval until June
	2019
Task 3d: Hazard Standard Modeling	Weekly deliverables after
	workplan approval until June
	2019
Task 3e: Clearance Standard Report	Monthly deliverables starting end
	of June until complete
Task 3f: Clearance Standard Modeling	Monthly deliverables starting end
	of June until complete
Task 4a: Model development and documentation	Within 1 month of receipt of
	technical direction

Task 4b: AALM-Fortran documentation, GUI, and sensitivity analysis	Within 2 months of receipt of
	technical direction

Note: All days are calendar days.

#### VI. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this TO before being approved as final.
- 2. The contractor shall comply with other applicable requirements for final TO reports stipulated in contract.

### VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or TO, the contractor shall immediately contact the PO, COR, or CO

#### VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA COR at the initiation of the TO and shall provide a biweekly update to the COR by telephone for the duration of the TO, in addition to the standard reporting requirements of the contract.

#### IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this TO shall be sent to the PO.

Task Order COR (COR): Evelyn Seel OPPT-RAD AB5 Seel.Evelyn@epa.gov 202-564-6289

## Appendix A

### **Quality Assurance Instructions for Contractors Citing Secondary Data**

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the duration of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding:

VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;

INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?

RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits enough depth of intellect rather than superficial or simplistic reasoning;

UTILITY: the work is useful and professionally relevant; it contributes to the field in terms of the practitioners' understanding or decision-making on the topic.

CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

#### DATA CHECKLIST FOR EVALUATING A STUDY

1.)	Bibliographic identification of the study.
	Study Identifiers: Author(s): Title: Study Citation: Storage location (e.g., library, facility archive, personal archive):
2.)	Why is the study key to the project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)
3.)	Summarize the study structure and methodology. What sampling techniques and statistical tests are used?
4.)	Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.
5.)	Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.
6.)	Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:
	Are research questions clearly stated; dependent and independent variables clearly defined?
	Do the authors explain the type of data obtained from measures of the variables?
	Are statistical methods adequately described; are they justified?
	Is a source provided for the any statistical software used to analyze the data?
	Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

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	RTP-Finance Center (AA216-01)				
	109 TW Alexander Drive				
	www2.epa.gov/financial/contracts				
	Durham NC 27711				
	Period of Performance: 07/02/2019 to 07/01/2020				
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2. AMENDMEN	NT/MODIFICATION NO.	3. EFFECTIVE	DATE	4. REQ	L UISITION/PURCHASE REQ. NO.	5. PR(	∠ DJECT NO. (If applicable)	
P00002		See Blo	ck 16C					
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CAD				CPOI				
	ronmental Protection	_			Environmental Protection			
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8. NAME AND	ADDRESS OF CONTRACTOR (No., street	, county, State and	ZIP Code)	ν) 9A.	AMENDMENT OF SOLICITATION NO.			
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	rporated, L.L.C. bert Toth			9B	DATED (SEE ITEM 11)			
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				10E	B. DATED (SEE ITEM 13)			_
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	5.D. orb. org. 50 JH - 50 orb.	11. THIS IT		/IENDM	ENTS OF SOLICITATIONS			—
The above n	numbered solicitation is amended as set for	orth in Item 14.	The hour and date specifie	ed for re	eceipt of Offers 🔲 is exter	nded.	☐ is not extended.	_
each letter o	or electronic communication makes referent TING AND APPROPRIATION DATA (If requedule	nce to the solicita uired)	ation and this amendment,	and is	may be made by letter or electronic communication received prior to the opening hour and date specified prior to the opening hour and date specified hour and the opening hour and date specified hour and date	ecified.		
CHECK ONE	A. THIS CHANGE ORDER IS ISSUED I ORDER NO. IN ITEM 10A.	PURSUANT TO:	(Specify authority) THE (	CHANG	ES SET FORTH IN ITEM 14 ARE MADE IN TH	HE CON	ITRACT	
Х	B. THE ABOVE NUMBERED CONTRAC appropriation data, etc.) SET FORTH	CT/ORDER IS M I IN ITEM 14, PU	ODIFIED TO REFLECT TI JRSUANT TO THE AUTH	HE ADI ORITY	MINISTRATIVE CHANGES (such as changes i OF FAR 43.103(b).	n payin	g office,	
	C. THIS SUPPLEMENTAL AGREEMEN	T IS ENTERED	NTO PURSUANT TO AU	THORI	TY OF:			
	D. OTHER (Specify type of modification	and authority)						—
E. IMPORTANT	Γ: Contractor X is not	is required t	o sign this document and	return	copies to the issuing	office.		_
14. DESCRIPT		(Organized by U	CF section headings, inclu	uding s	olicitation/contract subject matter where feasib	le.)		
TOCOR: S	SHEILA KRAGIE							
LIST OF	CHANGES:							
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Except as prov	vided herein, all terms and conditions of the	e document refe	erenced in Item 9 A or 10A	, as he	retofore changed, remains unchanged and in fo	ull force	and effect.	
15A. NAME AN	ND TITLE OF SIGNER (Type or print)			16A. I	NAME AND TITLE OF CONTRACTING OFFIC	ER (Ty	pe or print)	_
				Wil	liam M. Yates			
15B. CONTRA	CTOR/OFFEROR		15C. DATE SIGNED		JNITED STATES OF AMERICA		16C. DATE SIGNED	
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·	(Signature of person authorized to sign)			1.5	(Signature of Contracting Officer)	IGNAT	04/30/2020	

 CONTINUATION SHEET
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 PAGE 2
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NAME OF OFFEROR OR CONTRACTOR

EM NO.	SUPPLIES/SERVICES	QUANTITY		UNIT PRICE	AMOUNT
(A)	(B)	(C)	(D)	(E)	(F)
	Payment:				
	RTP Finance Center				
	US Environmental Protection Agency				
	RTP-Finance Center (AA216-01)				
	109 TW Alexander Drive				
	www2.epa.gov/financial/contracts				
	Durham NC 27711				
	Period of Performance: 07/02/2019 to 07/01/2020				
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2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE	DATE	4. REQ	UISITION/PURCHASE REQ. NO.	5. PR	JECT NO.	∠ (If applicable)		
P00003	See Bloo	ck 16C	PR-0	CSPP-20-00348					
6. ISSUED BY CODE	CAD		7. ADN	IINISTERED BY (If other than Item 6)	CODE	CPOD			
CAD US Environmental Protection 26 West Martin Luther King D Mail Code: W136 Cincinnati OH 45268-0001	_		CPOD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: NWD Cincinnati OH 45268						
8. NAME AND ADDRESS OF CONTRACTOR (No., street,	county. State and	ZIP Code)	. I9A	AMENDMENT OF SOLICITATION NO.					
ICF Incorporated, L.L.C. Attn: Robert Toth 9300 LEE HIGHWAY FAIRFAX VA 220316050	·	9B.  10A  68 68	DATED (SEE ITEM 11)  MODIFICATION OF CONTRACT/ORDER NOT HERC 19D0003  HERC 19F0213  DATED (SEE ITEM 13)	O.					
CODE 072648579	FACILITY COD	E		7/02/2019					
0/20403/3				ENTS OF SOLICITATIONS					
CHECK ONE  A. THIS CHANGE ORDER IS ISSUED FORDER NO. IN ITEM 10A.	DDIFICATION O PURSUANT TO: ET/ORDER IS MILLIN ITEM 14, PU	F CONTRACTS/ORDERS (Specify authority) THE CONTRACTOR OF T	. IT MC CHANG HE ADI	ES SET FORTH IN ITEM 14 ARE MADE IN THE MINISTRATIVE CHANGES (such as changes in FAR 43.103(b).	SCRIBE HE CON	NTRACT	14.		
D. OTHER (Specify type of modification	and authority)								
E.IMPORTANT: Contractor ⊠is not  14. DESCRIPTION OF AMENDMENT/MODIFICATION ( DUNS Number: 072648579  TOCOR: SHEILA KRAGIE  LIST OF CHANGES:  Reason for Modification: The amount of \$40,000 and to extend	Organized by U	of this modi	uding s	ation will be to add fur	le.)		:he		
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15A. NAME AND TITLE OF SIGNER (Type or print)	o accument tele	S. S. SOG III REIII J A OF TOA		NAME AND TITLE OF CONTRACTING OFFICE					
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15B. CONTRACTOR/OFFEROR		15C. DATE SIGNED			.CCYR(	ONIC	7/01/2020		
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 CONTINUATION SHEET
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 OF

 68HERC19D0003/68HERC19F0213/P00003
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NAME OF OFFEROR OR CONTRACTOR

EM NO.	SUPPLIES/SERVICES	QUANTITY		UNIT PRICE	AMOUNT
A)	(B)	(C)	(D)	(E)	(F)
	Obligated Amount for this Modification: \$40,000.00				
	CHANGES FOR LINE ITEM NUMBER: 1				
	Total Amount changed				
	from \$193,534.00 to \$233,534.00				
	Obligated Amount for this Modification: \$40,000.00				
	End Date changed from 01-JUL-20 to 01-JUL-21				
	NEW ACCOUNTING CODE ADDED:				
	Account code:				
	20-21-B-69A-000CD7-2505-TLRHZQA-2069AC2056-001				
	Beginning FiscalYear 20				
	Ending Fiscal Year 21				
	Fund (Appropriation) B				
	Budget Organization 69A				
	Program (PRC) 000CD7				
	Budget (BOC) 2505				
	Job # (Site/Project)				
	NO.				
	Cost Organization TLRHZQA				
	DCN-LineID 2069AC2056-001				
	Amount: \$40,000.00				
	Payment:  RTP Finance Center  US Environmental Protection Agency  RTP-Finance Center (AA216-01)  109 TW Alexander Drive  www2.epa.gov/financial/contracts  Durham NC 27711  Period of Performance: 07/02/2019 to 07/01/2021				
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IMPORTANT:	Mark all	packages and papers wit	h contract an	d/or ord	ler numbers.						1		2
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# ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION

PAGE NO

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IMPORTANT:	: Mar	k all packages and papers with contract and/or order numbers.									
DATE OF ORD		CONTRACT NO.				ORDER NO.					
07/09/20	19	68HERC19D0003	2			68HERC	:19F0216				
ITEM NO.		SUPPLIES/SERVICES	QUANTITY		16041210-0124		AMOUNT	QUANTITY			
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		US Environmental Protection Agency									
		26 West Martin Luther King Drive									
		Mail Code: NWD									
		Cincinnati OH 45268									
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0001	Cor	ntract 68HERC19D0003 TO-0017 Technical					192,276.00				
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\$192,276.00

## PERFORMANCE WORK STATEMENT CONTRACT NO. 68HERC19D0003

#### **TITLE: Technical Support for Risk Assessment Forum Documents**

Specify Section: PWS IIIA & IIIB

PERIOD OF PERFORMANCE: Award to 6/15/20

#### A. BACKGROUND

Federal regulatory agencies often rely on risk assessments as a primary component in their decision-making process. To ensure that assessments are conducted in a consistent and transparent manner the Environmental Protection Agency (EPA) develops guidelines, guidance documents and "white papers" to provide a framework for analyzing data. EPA's Risk Assessment Forum (RAF) is charged with coordinating the development of Agency-wide guidelines and guidance documents that provide that framework. The principal audiences for these products are IRIS and other EPA risk assessors and risk managers; however, these documents also provide clarity and transparency to the stakeholders and other interested parties and are often cited by other regulatory entities.

#### **B. PURPOSE**

Risk assessment guidelines and related products are among the important products developed by the EPA. These products inform risk assessors how to acquire data and apply it to risk assessments, promote consistency in Agency risk assessments and inform stakeholders and other interested parties of EPA risk assessment policies and practices. As such, these documents must be scientifically accurate and need to be written in a clear and concise manner.

This task order serves as a generic task with the intention that it will cover support for the development, revision and technical editing of several Risk Assessment Forum documents for which technical direction will be issued for each product. The technical direction accompanying each document will contain instructions specific to that product.

#### C. KNOWLEDGE AND SKILLS REQUIRED

The Contractor possess demonstrated experience in the production of quality scientifically accurate risk assessment methods and guidelines with an appropriate level of expertise in human health and ecological risk assessment methods and exposure science. Additionally, the Contractor shall have capacity for critiquing and technical editing of RAF documents for clarity and consistency, as well as grammatical editing. The Contractor shall be experienced with the use of Endnote database software and MS Word 2016. The Contractor shall also be proficient in developing and populating basic databases using MS Access 2016. The Contractor shall be competent in tracking meeting discussions and taking meeting notes. The level of expertise for each task will be commensurate with the technical direction.

#### D. TASKS

This work falls mainly under PWS Sections:

III A. Assessment Issues and Documents: The Contractor shall develop, revise, review and update, and/or evaluate various scientific documents and reports used by ORD to assess the nature and degree of risk posed by contaminants (chemical, physical, mixtures and biological/microbial) in a variety of media; and

III B. Risk Assessment Methods Research and Development: The Contractor shall provide scientific and technical support for the development of innovative human health risk assessment methodologies/procedures or the refinement and improvement of existing ones.

#### Task 1: Establish Communication

Within 3 days of start date of this TO, the Contractor shall schedule a conference call (not to exceed 1 hour) with the COR, workgroup members, and appropriate Contractor staff to clarify outstanding questions and confirm the schedule and specific tasks for the task order. Similarly, the Contractor shall initiate communication with the COR within three days of the issuance of any technical direction issued by the COR. The Contractor shall initiate additional communication with the COR should developments arise that will affect the conduct or schedule of the assignment.

## Task 2: Work Plan and Staffing Plan

The Contractor shall prepare a Technical Work Plan describing how the work outlined in the technical direction under this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel.

#### Task 3: Assemble Research Notes and Literature Sources on Uncertainty Factor Defaults

The Contractor shall receive assembled research notes and literature sources on the use of data base and subchronic to chronic uncertainty factor defaults, and working with identified EPA/RAF staff will prepare a report on the use of these uncertainty factors and what if any modifications to their standard use can be recommended, or what additional study is required to determine the adequacy of the use of these uncertainty factors by EPA. Sources for the final report were largely prepared by ICF and are currently in the possession of ICF managers. It is estimated that the completion of the report will require primarily P4 level expertise for an estimated 190 hours with support of P3 estimated at 140 hours. Sixty hours of additional junior support is expected. Comments will be received on the draft and the Contractor will, in conjunction with the RAF staff prepare a final report.

# Task 4: Provide Technical Support for Targeted Revisions to Cancer Guidelines and Development of a Framework for Non-Cancer Human Health Risk Assessment Guidelines

The Contractor shall assist the RAF in the revision to or development of guidelines for cancer and non-cancer human health risk assessment. Working with identified EPA/RAF staff the Contractor shall perform a review of scientific and government documents published in government or peer reviewed scientific literature since 2012 on chemical risk assessment focusing primarily on the dynamics (process) and components of chemical risk assessment (e.g., planning and scoping, problem formulation, data quality assessment, computation of metrics of risk (e.g., benchmark dose, RfD/RfC), assessment of variability and uncertainty, systematic review). This task is not evaluating assessment of specific endpoints (e.g., developmental, neurological, systemic toxicity). The Contractor shall prepare five (5) deliverables updating existing risk assessment methods or addressing new methods. An average of 20 hours/month at the P4 level will be required, in addition to technical editing of the documents.

#### Task 5. Technical Editing

The Contractor shall review and edit technical risk assessment documents provided by RAF staff addressing grammatical, syntax, and spelling errors, consistency in the use of terms, formatting and voice in the document with specific attention to the items listed in the technical direction. EPA will provide additional direction as to the specifics of the technical editing that will also include associated activities such as tabulating reviewers' comments on draft documents. The Contractor shall establish or maintain a database of references/citations in Endnote software. The Contractor shall maintain ongoing communication with the COR to ensure quality and timely completion of the project. This task will cover two rounds of review EPA's Guidelines for Human Exposure Assessment (about 250 pages).

### Task 6. Compilation of Comments

As per technical direction, the Contractor shall compile comments received during review of the three documents produced in task 3 and task 4 over the next twelve months. The Contractor shall assemble the comments in a format per technical direction. As appropriate and in consultation with the COR, comments of a similar vein shall be consolidated.

### Task 7. Delivery of the Final Product

The Contractor will receive final edits to the three documents for preparation of final revised drafts. The Contractor may deliver electronic versions (MS Word 2016 or as specified in the technical direction) of the final revised documents to the COR, alternate COR, and others designated in the technical direction including both clean and marked-up drafts: the latter shall be a revised document presented as a "track changes."

## **Task 8: Tracking Meeting Discussions**

The Contractor shall participate in meetings and take summary notes, send draft notes to the meeting chair, and receive edits to prepare a final draft of notes. There will be an average of 9 meetings per month through the end of the performance period.

#### E. SCHEDULE AND DELIVERABLES

Product	<b>Due Date</b>
Task 1. Initial Conference Call	3 days after award
Task 2. Staffing Plan	Per contact requirements
Task 3. Preparation of a report on the use of data base and sub-chronic to chronic	September 20, 2019
uncertainty factors.	
Task 4. Provide Technical Support for Targeted Revisions to Cancer Guidelines	As specified in the technical
and Development of a Framework for Non-Cancer Human Health Risk	direction.
Assessment Guidelines	
Task 5. Shall review and edit the document addressing grammatical, syntax, and	As specified in the technical
spelling errors that may exist in the document with specific attention to the items	direction.
listed in the technical direction laid out in the attachment.	
<b>Task 6.</b> Shall compile comments received during review of the document.	As specified in the technical
	direction.
Task 7. Shall deliver an electronic version (MS Word or as directed in the	As specified in the technical
technical direction) of the draft document to the COR, alternate COR, and others	direction.
designated in the technical direction including each in both clean and marked-up	
drafts: the latter shall be a revised document presented as a "track changes unless	
otherwise specified in the technical direction.	

Task 8. Tracking meeting discussions	As specified in the technical
	direction.

# F. Acceptance Criteria

Final products shall be produced by the Contractor upon the EPA TO COR's approval through written technical direction. The Contractor shall provide all materials written as part of these tasks to the EPA TO COR, as per work assignment, in electronic format. Electronic versions shall be in MS Word 2016, PowerPoint 2016 and Excel 2016 computer format unless otherwise specified in the technical direction.

#### **G. MANAGEMENT CONTROLS:**

Periodic meetings between the EPA and Contractor task order managers are encouraged to discuss any questions that may arise during performance or completion of this task order. At the EPA TO COR's discretion, these meetings may occur via teleconference or video conferences. The Contractor shall document these meetings and submit copies of this correspondence to the EPA TO COR.

The EPA TO COR may identify one or more EPA technical representatives for this task order. Interaction between the Contractor and any EPA technical representative(s) designated by the EPA TO COR is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this task order. The interaction will be technical communication via technical direction. Per the technical direction clause EPAAR 1552.237-71 of the contract, the EPA PO COR and the EPA TO COR or alternate EPA TO COR are the only representatives of the CO authorized to provide technical direction.

Per the technical direction clause, the CO and PO will be provided with copies of all technical direction.

#### H. CONFIDENTIALITY

Some of the information to be edited under this task may be internal information that is not ready for public distribution. The Contractor shall not discuss the contents of the document with anyone not specified as a participant in the document review process or its preparation.

### VI. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this task order before being approved as final.
- 2. The Contractor shall comply with other applicable requirements for final task order reports stipulated in contract.

#### NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or task order, the contractor shall immediately contact the PO, TO COR or CO

### SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA TO COR at the initiation of the task and shall provide a biweekly update to the TO COR by telephone for the duration of the task order, in addition to the standard reporting requirements of the contract.

### **EPA CONTACT INFORMATION**

Copies of all correspondence pertaining to the performance of this task order shall be sent to the PO.

# Task Order COR

### Task Order COR

Michael W. Broder Office of Science Advisor U.S. EPA (8105-R) Office of the Science Advisor 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460 Telephone: (202) 564-3393

Fax: (202) 564-2070

### **Alternate Task Order COR:**

Lawrence Martin Office of the Science Advisor U.S. EPA (8105-R) 1200 Pennsylvania Ave., NW Washington, DC, 20460 Telephone (202) 564-6497

Fax: (202) 564-2070

AMENDMENT OF SOLICITATION/MODIFICA	ATION OF CONTRACT		CONTRACT ID CODE	OF PAGES							
2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. RE0	L QUISITION/PURCHASE REQ. NO.	5. PROJEC	NO. (If applicable)						
P00001	See Block 16C	PR-C	DRD-20-00918								
6. ISSUED BY CODE	CAD	7. AD	MINISTERED BY (If other than Item 6)	CODE CE	OD						
CAD US Environmental Protection 26 West Martin Luther King D Mail Code: W136 Cincinnati OH 45268-0001	Agency	CPO US 26 Mai	CPOD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: NWD Cincinnati OH 45268								
8. NAME AND ADDRESS OF CONTRACTOR (No., street,	county State and ZIP Code)	194	. AMENDMENT OF SOLICITATION NO.								
CCF Incorporated, L.L.C. Attn: Robert Toth 0300 LEE HIGHWAY CAIRFAX VA 220316050	county, state and 211 codes	98 × 10 6	9B. DATED (SEE ITEM 11)								
CODE 072648579	FACILITY CODE		B. DATED (SEE ITEM 13) 17/09/2019								
CODE 072648579			MENTS OF SOLICITATIONS								
separate letter or electronic communication which incl RECEIVED AT THE PLACE DESIGNATED FOR THE OFFER. If by virtue of this amendment you desire to a each letter or electronic communication makes referent 12. ACCOUNTING AND APPROPRIATION DATA (If requised Scient Scien	udes a reference to the solicitati RECEIPT OF OFFERS PRIOR change an offer already submitte ce to the solicitation and this an dired)	ion and amendm TO THE HOUR ed , such change mendment, and is	AND DATE SPECIFIED MAY RESULT IN RE may be made by letter or electronic commun	WLEDGEMENT EJECTION OF Y nication, provide e specified.	TO BE DUR d						
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C. THIS SUPPLEMENTAL AGREEMEN		NT TO AUTHOR	TY OF:								
D. OTHER (Specify type of modification	and authority)										
E. IMPORTANT: Contractor X is not	is required to sign this docu	ıment and return	copies to the issu	uing office.							
14. DESCRIPTION OF AMENDMENT/MODIFICATION (DUNS Number: 072648579) FOCOR: MBRODER LIST OF CHANGES: Reason for Modification: The funding from this task order funding.	purpose of this	s modific	ation will be to de-ob	oligate F							
CHANGES FOR LINE ITEM NUMBER The following is the line of Continued	accounting for										
Except as provided herein, all terms and conditions of th 15A. NAME AND TITLE OF SIGNER ( <i>Type or print</i> )	e accument reterenced in Item 9	16A.	retofore changed, remains unchanged and in NAME AND TITLE OF CONTRACTING OF Lliam M. Yates								
15B. CONTRACTOR/OFFEROR	15C. DATE SIG	GNED 16B.	UNITED STATES OF AMERICA	ELECTRONIC SIGNATURE	16C. DATE SIGNED						
(Signature of person authorized to sign)			(Signature of Contracting Officer)		00/11/2020						

 CONTINUATION SHEET
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NAME OF OFFEROR OR CONTRACTOR

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(A)	(B)	(C)	(D)	(E)	(F)
	CHANGES FOR ACCOUNTING CODE:				
	19-20-C-26W1000-000F84-2532-26A5C-1926W1C930-003				
	Amount changed from \$44,647.00 to \$23,746.11				
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	The following is the line of accounting for the				
	obligation of FY 20/21 funding:				
	NEW ACCOUNTING CODE ADDED:				
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	20-21-C-2632000-000FK6XR2-2532-26A5C-202632E003-00				
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	Beginning FiscalYear 20				
	Ending Fiscal Year 21				
	Fund (Appropriation) C				
	Budget Organization 2632000				
	Program (PRC) 000FK6XR2				
	Budget (BOC) 2532				
	Job # (Site/Project)				
	Cost Organization 26A5C				
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	Amount: \$20,900.89				
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	Payment:  RTP Finance Center				
	US Environmental Protection Agency				
	RTP-Finance Center (AA216-01)				
	109 TW Alexander Drive				
	www2.epa.gov/financial/contracts				
	Durham NC 27711				
	Period of Performance: 07/09/2019 to 07/08/2020				
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AMENDMENT OF SOLICITATION/MODIFIC.	ATION OF CO	ONTRACT		CONTRACT ID CODE		PAGE OF PAGES					
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8. NAME AND ADDRESS OF CONTRACTOR (No., street	, county, State and .	ZIP Code)	(V) 9A.	AMENDMENT OF SOLICITATION NO.							
ICF Incorporated, L.L.C. Attn: Robert Toth 9300 LEE HIGHWAY FAIRFAX VA 220316050		9B. DATED (SEE ITEM 11)  x 10A. MODIFICATION OF CONTRACT/ORDER NO. 68HERC19D0003 68HERC19F0216 10B. DATED (SEE ITEM 13)									
CODE 072648579	FACILITY CODE			7/09/2019							
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C. THIS SUPPLEMENTAL AGREEMEN  D. OTHER (Specify type of modification		NTO PURSUANT TO AU	THORIT	Y OF:							
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Continued  Except as provided herein, all terms and conditions of the	ne document refer	renced in Item 9 A or 10A	, as her	etofore changed, remains unchanged and in	full force	and effect.					
15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) William M. Yates								
15B. CONTRACTOR/OFFEROR		15C. DATE SIGNED	16B. U	INITED STATES OF AMERICA	LECYRO	16C. DATE SIGNED					
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NAME OF OFFEROR OR CONTRACTOR

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	Payment:				
	RTP Finance Center				
	US Environmental Protection Agency				
	RTP-Finance Center (AA216-01)				
	109 TW Alexander Drive				
	www2.epa.gov/financial/contracts				
	Durham NC 27711				
	Period of Performance: 07/09/2019 to 07/08/2021				
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Attn: Robert Toth			9B.	DATED (SEE ITEM 11)						
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FAIRFAX VA 220316050		-	104	MODIFICATION OF CONTRACT/ORDER NO	0					
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Items 8 and 15, and returning consequence separate letter or electronic communication which inc RECEIVED AT THE PLACE DESIGNATED FOR THE OFFER. If by virtue of this amendment you desire to each letter or electronic communication makes refere 12. ACCOUNTING AND APPROPRIATION DATA (If reg.	ludes a reference ERECEIPT OF O change an offer a nce to the solicita	to the solicitation and am FFERS PRIOR TO THE H already submitted, such ci tion and this amendment,	endme OUR A nange and is	ND DATE SPECIFIED MAY RESULT IN REJE may be made by letter or electronic communica received prior to the opening hour and date sp	EDGEM CTION ation, pr ecified.	MENT TO BE OF YOUR ovided				
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15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)							
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15B. CONTRACTOR/OFFEROR		15C. DATE SIGNED	16B. I	JNITED STATES OF AMERICA		16C.	. DATE SIGNED			
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(Signature of person authorized to sign)	*			(Signature of Contracting Officer)			3/07/2020			

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NAME OF OFFEROR OR CONTRACTOR

ITEM NO.	SUPPLIES/SERVICES	QUANTITY		UNIT PRICE	AMOUNT
(A)	(B)	(C)	(D)	(E)	(F)
	Payment:  RTP Finance Center  US Environmental Protection Agency  RTP-Finance Center (AA216-01)  109 TW Alexander Drive  www2.epa.gov/financial/contracts  Durham NC 27711  Period of Performance: 07/09/2019 to 07/08/2021				
0002	Contract 68HERC19D0003 TO-004 Task 4: Provide Technical Support for Targeted Revisions to Cancer Guidelines and Development of a Framework for Non-Cancer Human Health Risk Assessment Guidelines				191,515.0
	Accounting Info: 20-21-C-2632000-000FK6XR2-2532-26A5C-202632E004-001 1 BFY: 20 EFY: 21 Fund: C Budget Org: 2632000 Program (PRC): 000FK6XR2 Budget (BOC): 2532 Cost: 26A5C DCN - Line ID: 202632E004-001 Funding Flag: Complete Funded: \$0.00 Accounting Info: 20-21-C-2632000-000FK8XPV-2532-26A5C-202632E004-00 2 BFY: 20 EFY: 21 Fund: C Budget Org: 2632000 Program (PRC): 000FK8XPV Budget (BOC): 2532 Cost: 26A5C DCN - Line ID: 202632E004-002 Funding Flag: Complete Funded: \$70,000.00 Accounting Info: 20-21-C-2632000-000FK8XPW-2532-26A5C-202632E004-00 3 BFY: 20 EFY: 21 Fund: C Budget Org: 2632000 Program (PRC): 000FK8XPW Budget (BOC): 2532 Cost: 26A5C DCN - Line ID: 202632E004-003 Funding Flag: Complete Funded: \$121,515.00				

ORDER FOR SUPPLIES OR SERVICES											PAGE (	F PAGES	3
IMPORTANT:	Mark all	packages and papers w	ith contract	and/or ord	der numbers.	10					1		2
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# ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER CONTRACT NO.

PAGE NO

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ORDER NO.

07/24/2	019 68HERC19D0003			68HE	RC19F0224				
ITEM NO.	SUPPLIES/SERVICES	QUANTITY	12(2) 15(2) 16	UNIT	AMOUNT	QUANTITY			
(a)	(b)	ORDERED (c)	(d)	PRICE (e)	(f)	ACCEPTED (g)			
ITEM NO.	SUPPLIES/SERVICES	ORDERED	125108-15	UNIT PRICE	AMOUNT	ACCEPTED			
	19262SC902-004 Funding Flag: Complete Funded: \$250.00								
	TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))		_		\$251,412.00				

# PERFORMANCE WORK STATEMENT CONTRACT NO. 68HERC19D0003 Task Order 68HERC19F0224

**TITLE:** Support for the IRIS Toxicological Review of Polychlorinated Biphenyls (PCBs): Effects Other Than Cancer

**Specify Section & Paragraph SOW:** A1. Assessment Issues and Documents. Human Health Assessment Documents

**Period of PERFORMANCE:** Award through 1 year

# I. PURPOSE

The purpose of this Task Order (TO) is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA) in support of the development of health assessments.

# II. BACKGROUND

The National Center for Environmental Assessment (NCEA), a major component of EPA's Office of Research and Development (ORD), with headquarters in Washington, DC, is EPA's national resource center for human health and ecological risk assessment. NCEA occupies a critical position in ORD between researchers in other parts of ORD and outside of EPA who are generating new findings and data, and the regulators in EPA's program offices and regions who must make regulatory, enforcement, and remedial action decisions. NCEA prepares technical reports and assessments that integrate and evaluate the most up-to-date research and serve as major elements of the science foundation supporting EPA policies. As a result, NCEA plays an important role as a consultant to EPA programs and regions on the use of science in environmental decision making and also influences the direction of environmental research.

# III. STATEMENT OF WORK

The purpose of this TO is to assist in the development of the *Toxicological Review of Polychlorinated Biphenyls* (PCBs): Effects Other Than Cancer and other related assessment materials.

### Task 1: Establish Communication

Within 3 days of the TO award, the Contractor shall schedule a conference call (not to exceed 1 hour) with the TO Contracting Officer Representative (TOCOR) and other EPA staff and any appropriate contractor staff to clarify outstanding questions and confirm the schedule of specific tasks. The TOCOR will submit the work requests via a Technical Directive. This technical directive will be used as instructions to the Contractor and will be submitted with each request. The Contractor will provide a cost estimate of work submitted under each technical directive. Copies of all correspondence pertaining to the performance of this TO shall be sent to the CL-COR.

**Deliverable:** Schedule and participate in the conference call.

Task 2: Quality Assurance Project Plan (QAPP)

The Contractor shall develop a QAPP for approval by the TOCOR and Quality Assurance Manager. The Contractor shall not perform any work on subsequent tasks under this TO until the QAPP is reviewed and approved.

The Contractor must ensure that all data collected, generated or used are of the appropriate type and quantity needed and of known, documented, and adequate quality. This statement of applicability conforms to the Agency's requirements. The Contractor must submit a QAPP that addresses data generation, collection, use, and analysis. The QAPP should include a description of quality control checks to verify accuracy, completeness, and adherence to established format. The Contractor must address in the QAPP how existing data will be considered for the TO. Existing (secondary) data is defined as the use of data that was developed for a different purpose and includes data in the published literature. The QAPP shall be in conformance with EPA's Requirements for Quality Assurance Project Plans (EPA QA/R-5). Guidance for developing QAPPs that meet EPA specifications prepared for activities conducted by or funded by EPA, are available online at <a href="http://www.epa.gov/quality/qa\_docs.html">http://www.epa.gov/quality/qa\_docs.html</a>, see "EPA Requirements for Quality Assurance Project Plans (QA/R-5)".

The contractor shall include, "EPA QA Tracking number B-IRISD-0031956-QP-1-0" on the title page of the QAPP.

**Deliverable:** Develop QAPP for approval by EPA.

# Task 3: Identification, Prioritization, and Synthesis of Information Related to PCB Absorption, Distribution, Metabolism, and Excretion (ADME), Kinetic Modeling, Mode of Action, and Susceptible Populations and Lifestages

Specific instructions will be provided by the TOCOR through technical directives. It is expected that there will be approximately 5 separate requests for this task.

# (1) <u>Identify literature</u>

- Perform and update electronic search using specified bibliographic databases
- Databases used should be consistent with the current version of the draft IRIS Handbook and with the draft document.
- Search terms should be selected in close collaboration with the EPA assessment team.
- Use additional search strategies as identified in the draft IRIS Handbook, including (but not limited to) "forward" and "backward" searching based on articles identified as key studies.

### (2) Screen references for relevance

- Screen, with separation (or binning) of references into categories consistent with the approach outlined in the current version of the draft IRIS Handbook and with the draft document.
- Develop or assign a list of tags (or bins) for sorting references in HERO. The list of tags should be generated in close collaboration with the EPA assessment team.
- Use automated tools such as SWIFT Active Screener as directed
- Update HERO project page with chemical-specific tags.

# (3) Develop (and update) literature inventories

• Based on the results of a literature search and screen, add selected studies to a database with defined data fields and keywords as specified by the EPA (e.g., fields could include study type, methods, health outcome). EPA will provide templates for new inventories and existing inventories for updates.

# (4) Document the literature search strategy and results

- Document search strings, results (number of citations), and date of searches.
- Provide tabular summaries of the literature search strategy.
- Revise literature search flow diagrams showing results of the updated search based on computerized keyword search and screen, forward/backward search of relevant articles, title/abstract screen, and full text screen.

### (5) Prioritize studies for inclusion in text syntheses

• Evaluate identified studies according to criteria provided by EPA

# (6) Develop synthesis text

Describe the available data associated with exposure to PCBs, focusing on studies prioritized as
described above and in technical directives.

**Deliverable:** Deliverable format and schedule will be defined in technical directives.

# IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, MS Word documents, PDFs, HERO).

# V. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this TO before being approved as final.
- 2. The Contractor shall comply with other applicable requirements for final TO reports stipulated in contract.

# VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The Contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the Contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or TO, the Contractor shall immediately contact the CL-COR, TOCOR, or CO.

The Contractor shall also ensure that work under this TO does not contain any apparent or real personal or organizational conflict of interest. The Contractor shall certify that none exist at the time the proposal is submitted to EPA.

# VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The Contractor shall hold a conference call with the TOCOR at the initiation of the TO. Standard reporting requirements of the contract apply for active/completed projects.

# VIII. OTHER REQUIREMENTS

The TOCOR will have oversight on all materials developed by the Contractor. The primary communication mechanism between the TOCOR and the Contractor shall be email.

In cases where the work to be performed is of a highly scientific or technical nature or requires consultation or interactions, it may be more expedient for the Contractor to interact directly with members of the scientific/technical staff.

# IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this TO shall be sent to the CL-COR.

# **TOCOR**:

Geniece M. Lehmann, Ph.D. U.S. EPA/ORD/NCEA MD B243-01 Research Triangle Park, NC 27711 <u>Lehmann.Geniece@epa.gov</u> (919) 541-2289

# **Alternate TOCOR:**

Laura Carlson, Ph.D.
U.S. EPA/ORD/NCEA
MD B243-01
Research Triangle Park, NC 27711
Carlson.Laura@epa.gov
(919) 541-0725

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6. ISSUED BY CODE	CAD		7. ADN	INISTERED BY (If other than Item 6)	CODE							
CAD US Environmental Protection 26 West Martin Luther King D Mail Code: W136 Cincinnati OH 45268-0001												
8. NAME AND ADDRESS OF CONTRACTOR (No., street	county State and 2	IP Code)	ΙαΔ	AMENDMENT OF SOLICITATION NO.								
ICF Incorporated, L.L.C. Attn: Robert Toth 9300 LEE HIGHWAY FAIRFAX VA 220316050	county, State and 2	-	9B. DATED (SEE ITEM 11)  x 10A. MODIFICATION OF CONTRACT/ORDER NO. 68HERC19D0003 68HERC19F0224									
CODE 072648579	FACILITY CODE	:		DATED (SEE ITEM 13) 7/24/2019								
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separate letter or electronic communication which incl RECEIVED AT THE PLACE DESIGNATED FOR THE OFFER. If by virtue of this amendment you desire to each letter or electronic communication makes referer 12. ACCOUNTING AND APPROPRIATION DATA (If requ See Schedule  13. THIS ITEM ONLY APPLIES TO M	udes a reference RECEIPT OF OF change an offer al nce to the solicitat uired)	to the solicitation and am FERS PRIOR TO THE H ready submitted , such c ion and this amendment, Net	endme IOUR A hange and is Inc	ND DATE SPECIFIED MAY RESULT IN REJE may be made by letter or electronic communica received prior to the opening hour and date sp rease: \$3  DIFIES THE CONTRACT/ORDER NO. AS DES	EDGEME CTION C ation, pro- ecified. 39,12	ENT TO BE DF YOUR vided 3.00 DIN ITEM 14.						
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NAME OF OFFEROR OR CONTRACTOR

EM NO.	SUPPLIES/SERVICES	QUANTITY		UNIT PRICE	AMOUNT
A)	(B)	(C)	(D)	(E)	(F)
	Obligated Amount for this Modification: \$39,123.00				
	New Total Obligated Amount for this Award:				
	\$290,535.00				
	CHANGES FOR LINE ITEM NUMBER: 1				
	Total Amount changed				
	from \$251,412.00 to \$290,535.00				
	Obligated Amount for this Modification: \$39,123.00				
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	CHANGES FOR RELIVERY LOCATION, ORD/OARS/EMB/SIN				
	CHANGES FOR DELIVERY LOCATION: ORD/OARS/EMD/CIN				
	Amount changed from \$251,412.00 to \$290,535.00				
	NEW ACCOUNTING CODE ADDED:				
	Account code:				
	19-20-C-262R000-000F84-2532-26A6A-19262RC921-001				
	Beginning FiscalYear 19				
	Ending Fiscal Year 20				
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	Program (PRC) 000F84				
	Budget (BOC) 2532				
	Cost Organization 26A6A				
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	109 TW Alexander Drive				
	www2.epa.gov/financial/contracts				
	Durham NC 27711				
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	US Environmental Protection Agency				
	RTP-Finance Center (AA216-01)				
	109 TW Alexander Drive				
	www2.epa.gov/financial/contracts				
	Durham NC 27711				
	Period of Performance: 07/24/2019 to 07/23/2020				

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# ORDER FOR SUPPLIES OR SERVICES SCHEDULE - CONTINUATION

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER CONTRACT NO.

PAGE NO

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ORDER NO.

07/30/20	/2019 68HERC19D0003				68HERC19F0226			
ITEM NO.	SUPPLIES/SERVICES	QUANTITY	12,2015,00	UNIT	140 No. 12 P. 12 P	QUANTITY		
(a)	(b)	(c)	(d)	(e)	(f)	(g)		
(a)	Admin Office:  CAD  US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: W136 Cincinnati OH 45268-0001 Period of Performance: 07/30/2019 to 07/29/2020  68HERC19D0003 TO-0004 Document Compilation and Toxicology Data Extraction for Curation of Studies, Journal Articles, Reports and Other Documents for ToxValDB and ToxRefDB  Funds were deobligated from an HHS/PSC Interagency Assisted Acquisition per the June 14, 2019 memo from HHS/PSC to non-DOD			PRICE (e)				
	customers, and were not received in time to recommit and release them to OAS by June 28, 2019. The funds are on the exception list and OAS has agreed to process after the June 28, 2019 deadline, as long as the action can be processed within PALT. If there are additional questions, please contact Tommie Madison.							
	Accounting Info:  19-20-C-2660000-000FK9XR6-2532-26A6A-1  92660E071-001 BFY: 19 EFY: 20 Fund: C  Budget Org: 2660000 Program (PRC):  000FK9XR6 Budget (BOC): 2532 Cost:  26A6A DCN - Line ID: 192660E071-001  Funding Flag: Complete  Funded: \$1,101,928.51  Accounting Info:  18-19-C-2660000-000FK9XR6-2532-26A6A-1							
	92660E071-002 BFY: 18 EFY: 19 Fund: C Budget Org: 2660000 Program (PRC): 000FK9XR6 Budget (BOC): 2532 Cost: 26A6A DCN - Line ID: 192660E071-002 Funding Flag: Complete Funded: \$85,644.49							
	TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))				\$1,187,573.00			

# PERFORMANCE WORK STATEMENT CONTRACT NO. 68HERC19D0003

# TO: 68HERC19F0226 Human Health and Risk Assessment

**TITLE**: Document Compilation and Toxicology Data Extraction for Curation of Studies, Journal Articles, Reports and Other Documents for ToxValDB and ToxRefDB

Specify Section & Paragraph SOW: C. Risk Assessment Data Bases and Computer Tools

PERIOD of PERFORMANCE: Award to 12 Months

#### I. PURPOSE.

The purpose of this task order is to obtain technical support services to the US Environmental Protection Agency's (EPA), Office of Research and Development (ORD), National Center for Computational Toxicology (NCCT) to compile documents, extract data and curate available legacy toxicity information from published journal articles, other study reports, data evaluation records (provided by EPA) and to locate primary study documents for data that was already extracted from other sources.

### II. BACKGROUND AND OBJECTIVES

The EPA Office of Research and Development's National Center for Computational Toxicology is developing multiple databases containing information on chemical properties, toxicology, toxicokinetics and exposure. Much of this information is taken from public sources (websites, journal articles, database download files) and information submitted to EPA to register chemicals. Many of the sources from which information is pulled are secondary, meaning that there was manual extraction of the source primary documents into the data sources that NCCT accesses. NCCT needs to evaluate the accuracy of the final compiled database relative to the original primary source documents as well as compile the original documents sources, extract additional data, automate. Where possible, NCCT would also like to automate the curation and data extraction process for this type of data. This Statement of Work (SOW) outlines tasks for a contractor to assist with this project.

#### III. STATEMENT OF WORK.

The Contractor shall provide all technical support within the scope of this Performance Work Statement (PWS). The Contractor shall perform tasks, as specified by this task order issued by the CO. A summary of each task is provided below, including the time frame during which the task shall be completed.

# Task 1. The contractor shall establish communication, submit a proposal, and arrange for routine updates for the EPA Task Order Contracting Officer's Representative (TO COR).

The contractor should review this Performance Work Statement and the associated source documents that need to be located, compiled and curated as well as the data that needs to be extracted. Based on the review, the contractor shall provide a plan to EPA which describes the estimated timelines for each task below. The contractor and EPA should have 2-4 conference calls per month to discuss priorities and timelines for data extraction, questions regarding extraction of some studies, and the status of document collection and data extractions.

**Deliverable 1**: The contractor shall provide a plan with an estimated timeline for completion of the tasks in this performance work statement.

**Deliverable 2**: The contractor shall coordinate regular conference calls with EPA NCCT to discuss the progress and timelines associated with the document compilation and data extraction. During these calls, the contractor should discuss any issues encountered.

# Task 2. The contractor shall locate and index source documents and pdf files.

For QA against primary sources, the NCCT needs source documents (primarily journal articles and study reports) compiled and registered. The NCCT will provide a list of source document information, such as titles of articles, in a spreadsheet. The contractor shall retrieve these articles as pdf files, name the files in a consistent manner and place put them into a single folder. The file naming convention should be consistent to allow for automation of the process. If the source documents are not available, a PDF copy of the website or secondary source shall be added to the folder if it can be identified. The contractor shall make every effort possible to obtain the documents. Not all documents will be publicly available, so the contractor is expected to make a best effort to find the documents, including the purchase of subscriptions to journals or other types of publications if needed. The number of initial document references is expected to be ~20,000.

**Deliverable 3**: The contractor shall provide a single folder containing PDF files of all requested source documents and if source documents are not available a PDF copy of the website or secondary source. Using a consistent file naming convention, the file names should be used and listed in the spreadsheet of source documents to link the spreadsheet to the file of documents.

**Deliverable 4:** The contractor shall provide periodic updates to the source index file and the located documents. Where possible, the contractor should develop scripts to automate the process of updating the source index file.

**Deliverable 5:** The contractor shall deposit all code built to automate the data acquisition on a Git Hub repository.

**Deliverable 6:** The contractor shall provide a written quality assurance plan for the document compilation, registration and indexing.

**Deliverable 7:** The contractor shall provide a **monthly** summary of the studies/data evaluation records reviewed and extracted, and any issues associated with the document location process.

# Task 3. The contractor shall extract quantitative study endpoint data and study metadata from provided journal manuscripts and study reports using HAWC.

For a separate set of documents (journal papers and study reports), the NCCT needs quantitative toxicity data and study metadata extracted using the HAWC tool. We anticipate that there will be approximately 1,000 documents to extract. NCCT will provide full pdfs of documents, and the contractor shall extract appropriate fields into HAWC. Contract staff performing the data extraction must show proficiency in using HAWC through evidence of training. The contractor shall perform sample checks on the primary extraction process to evaluate accuracy and completeness of the work of the primary extractors. The NCCT will then extract data from the HAWC database using HAWC web services. A second level of QC will be carried out by NCCT examining the completeness of the extracted information retrieved through these web services.

**Deliverable 8**: The contractor shall extract documents using HAWC standard operating procedures (SOPs) and will report to EPA when batches of studies are complete.

**Deliverable 9**: The contractor shall review the extraction of a fraction of studies (TBD) and report on accuracy and completeness. Personnel with high rates of errors or lack of completeness shall be retrained until they meet minimum proficiency requirements. NCCT will periodically provide feedback on the data accuracy for continuous data extraction/curation improvements.

**Deliverable 10:** The contractor shall provide a written quality assurance plan for the data extraction process, including a primary, secondary, and management level (to resolve conflicts) review.

**Deliverable 11:** The contractor shall provide a **monthly** summary of the studies/data evaluation records reviewed and extracted, and any issues associated with the extraction process.

# Task 4: The contractor shall index data evaluation record files for detailed extraction in Task 5.

The ToxRefDB currently stores roughly 6000 animal toxicology studies in a relational database with controlled vocabularies. Over 1000 chemicals have at least one study in the database. The goal of Task 4 is to index the data evaluation records available for a detailed data extraction described in Task 5.

The contractor shall assist the EPA by reviewing a repository of data evaluation records provided in various file formats (including PDF) to create an index that includes:

- (a) The MRID or data evaluation record identifier;
- (b) The study type and guideline number; and,
- (c) The chemical substance tested.

The EPA anticipates this activity will take approximately 5 minutes per study record/data evaluation record and necessitate a single reviewer as the records shall be reviewed again in Task 5. The number of available data evaluation records may be as high as 800.

**Deliverable 12:** Provide an index of the MRID/identifier, study type, guideline number, and chemical substance tested for a repository of data evaluation records provided to the contractor. Periodic updates of this index may be requested.

**Deliverable 13:** If appropriate given the source files provided, the contractor shall develop a text mining script (using R or Python) to extract study metadata from the source files to create the index described here. The contractor shall deposit all code built to automate the data acquisition on a Git Hub repository.

# Task 5. The contractor shall extract study metadata and quantitative dose-response information from provided data evaluation records (DERs) and study reports using Database files in support of ToxRefDB, including capturing tested and reported status for all observations.

The ToxRefDB currently stores roughly 6000 animal toxicology studies in a relational database with controlled vocabularies. Over 1000 chemicals have at least one study in the database. The goal of Task 5 is to increase the number of chemicals and studies in ToxRefDB with associated dose-response and observation status data. ToxRefDB, in addition to using controlled vocabularies, also includes dose-response information with the goal of performing dose-response modeling (e.g., benchmark dose modeling) to determine more quantitative points of departure. The contractor shall enter into the database quantitative dose-response information from the DERs. For example, a study was run at 3 doses plus controls with male and female groups. The NOAEL was established at 10 mg/kg/day and the LOAEL at 100 mg/kg/day based on liver weight gain in males and females, liver hypertrophy in males and females, and thyroid hyperplasia in the males. Additionally, spleen weight increase was observed and deemed treatment-related in the high dose group at 1000 mg/kg/day. With this

example, the contractor shall enter the group mean and standard deviation for liver and spleen weights and incidence information for liver hypertrophy and thyroid hyperplasia at each dose level and for the control group(s).

The contractor shall assist EPA by reviewing data evaluation records provided by the Office of Pesticide Programs to NCCT. The contractor will extract the:

- (a) Study metadata;
- (b) the no observed adverse effect level (NOAEL) and lowest observable adverse effect level (LOAEL) determinations based on the critical effect(s) from the data evaluation record;
- (c) other treatment-related effects, including those that are statistically significant and denoted as the lowest effect level (LEL);
- (d) quantitative dose-response information, defined as incidence and/or mean +/- standard deviation, and sample size, as well as any other necessary fields mutually decided, for each treatment group, including the control group, for all effects tagged treatment-related and/or critical in the study;
- (e) the testing status of all observations (e.g., tested, not tested, not reported);

The contractor shall open the data evaluation records, housed at the EPA, and perform a full data extraction as described above using database files supplied by the EPA. This data extraction shall follow quality assurance procedures, including a primary and secondary review followed by manager sign-off. The EPA estimates the review process to take roughly 2 hours per data evaluation record, on average, with a secondary review taking roughly 1 hour per study. The number of available data evaluation records may be as high as 800.

**Deliverable 14:** The contractor shall provide a written quality assurance plan for the data extraction process, including a primary, secondary, and management level (to resolve conflicts) review.

**Deliverable 15:** The contractor shall provide a **monthly** summary of the studies/data evaluation records reviewed and extracted, and any issues associated with the extraction process.

**Deliverable 16:** The contractor shall provide completed database files for import into ToxRefDB. If needed, the contractor will work with EPA to try to use a new data extraction tool technology to evaluate whether it can be used for this application.

# Task 6. Identification of Critical Effect(s) and Establishment of Study-Level Lowest-Observed-Adverse-Effect Level (LOAEL) Values

It is possible that data curation in Task 5 for ToxRefDB could be extended beyond data evaluation records from OPP. Data evaluation records from OPP have already been annotated for critical effects, and do not require Task 6 (as these critical effect information can be simply extracted). However, for source documents from other sources such as literature from PubMed or studies from the National Toxicology Program, the term "critical effect" is not used to define an adverse dose level. In Task 6, from all previously identified treatment-related effects, the Contractor shall use expert judgment (augmented by the "Determination of Critical Effects and Study Level NOAEL & LOAEL" and "Instructions for Critical Effect Determination" documents previously developed by the Contractor) to identify the critical effect(s) to establish study-level LOAEL values on a study-by-study basis for studies that do not already have a critical effect determination.

The critical effect(s) used to identify the study-level LOAEL shall be denoted by "checking" the box of the Boolean (yes/no) "critical effect" field in the edited/amended database deliverables. "NULL" value entries for a given treatment group indicate that no treatment-related effects were observed. A brief rationale/narrative regarding the choice of the critical effect(s) and establishment of the study-level LOAEL value shall be provided in the "dose comment" field on a study-by-study basis. Additionally, in the process of determining the

critical effect(s) to establish study-level LOAEL values, any remarks on the treatment-relatedness of the observed effects (previously determined) should be documented in the "effect comment" field.

For all multigeneration reproductive toxicity studies (denoted as "MGR") identified in the "study type" field, treatment-related effects were further identified as either a "Parental", "Reproductive", or "Offspring" effect category. Thus, "Parental", "Reproductive", and "Offspring" study-level LOAEL values should be identified whenever applicable on a study-by-study basis. Similarly, for all prenatal developmental toxicity studies (denoted as "DEV") in the "study type" field, treatment-related effects were further identified as either a "Maternal" or "Developmental" effect. Thus, "Maternal" and "Developmental" study-level LOAEL values should be identified whenever applicable on a study-by-study basis.

Although cancer effects are associated with some studies, study-level LOAEL values should <u>not</u> be identified based on cancer effects. However, dose-related incidence information [e.g., "at doses  $\geq$  100 mg/kg-day, hepatocellular adenomas (7/10 male rats") and carcinomas (3/10 male rats) were observed after 2-years of exposure] for any statistically or biologically significant tumor type should be captured in the "study comment" field in the edited/amended database deliverables. Deliverable 17: New critical effect determinations made for source documents that are not OPP data evaluation records will be documented in the extraction tool used in Deliverable 16 (critical effects already determined by OPP will simply be extracted in Task 5 and do not activate Task 6).

### IV. SUMMARY TIME TABLE.

Task	Task Title	Time frame
1	Establish communication via conference call	Ongoing
2	Locate and index source documents and pdf files	6-18 weeks
3	Extract quantitative study endpoint data and study metadata from provided journal manuscripts and study reports using HAWC	6-18 weeks
4	Index data evaluation record files for detailed extraction in Task 5	6-18 weeks
5	Extract study metadata and quantitative dose-response information from provided data evaluation records (DERs) and study reports using Microsoft Access Database files in support of ToxRefDB	6-18 weeks
6	Identification of Critical Effects and Lowest Observed Adverse Effect Level	6-18 weeks

1. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

- 2. All deliverables shall be in conformance with the requirements of the task order before such deliverables are approved as final. Electronic copy of all deliverable shall be sent to the EPA WA COR and technical representative, TBD.
- 3. The contractor shall comply with other applicable requirements for final task order reports as stipulated in the Contractual Agreement.
- 4. The contractor shall prepare all deliverables in accordance with the Quality Management Plan for the contract.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				CONTRACT ID CODE	PAGE OF PAGES		
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8. NAME AND ADDRESS OF CONTRACTOR (No., stre	et, county, State and	ZIP Code)	(v) 9A.	AMENDMENT OF SOLICITATION NO.			
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NY - 4.3	11. THIS IT	 EM ONLY APPLIES TO AM		ENTS OF SOLICITATIONS			
CHECK ONE A. THIS CHANGE ORDER IS ISSUED ORDER NO. IN ITEM 10A.	modification of pursuant to:  ACT/ORDER IS MITHER THE M	etion and this amendment, Net F CONTRACTS/ORDERS. (Specify authority) THE CONTRACTS THE AUTHORITY OF THE AUTHORITY THE AUTHORITY OF THE AUTHOR	, and is Dec  THANG  THE ADM  ORITY	received prior to the opening hour and date sprease:  DIFFIES THE CONTRACT/ORDER NO. AS DE ES SET FORTH IN ITEM 14 ARE MADE IN TO MINISTRATIVE CHANGES (such as changes to OF FAR 43.103(b).	SCRIBE	87, 573.00 ED IN ITEM 14.	
D. OTHER (Specify type of modification	on and authority)						
E. IMPORTANT: Contractor X is not	is required	to sign this document and	return	copies to the issuing	g office.		
14. DESCRIPTION OF AMENDMENT/MODIFICATION DUNS Number: 072648579 TOCOR: MONICA LINNENBRINK M LIST OF CHANGES: Reason for Modification: Ot task order and will enable order in order to utilize a	ax Expire her Admin the CO to	Date: 07/29/ istrative Act execute a ne	2020 ion w ta	) . This modification wi ask	11 c		
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				liam M. Yates			
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(Signature of Contracting Officer)

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NAME OF OFFEROR OR CONTRACTOR

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	RTP Finance Center				
	US Environmental Protection Agency				
	RTP-Finance Center (AA216-01)				
	109 TW Alexander Drive				
	www2.epa.gov/financial/contracts				
	Durham NC 27711				
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	Period of Performance: 07/30/2019 to 07/29/2020				
0001	68HERC19D0003 TO-0004 Document Compilation and				0.0
3001	Toxicology Data Extraction for Curation of				0.0
	Studies, Journal Articles, Reports and Other				
	Documents for ToxValDB and ToxRefDB				
	bocuments for loxvalbb and loxkelbb				
	Funds were deobligated from an HHS/PSC				
	Interagency Assisted Acquisition per the June 14,				
	2019 memo from HHS/PSC to non-DOD customers, and				
	were not received in time to recommit and release				
	them to OAS by June 28, 2019. The funds are on				
	the exception list and OAS has agreed to process				
	after the June 28, 2019 deadline, as long as the				
	action can be processed within PALT. If there				
	are additional questions, please contact Tommie				
	Madison.				
	Accounting Info:				
	19-20-C-2660000-000FK9XR6-2532-26A6A-192660E071-00				
	1 BFY: 19 EFY: 20 Fund: C Budget Org: 2660000				
	Program (PRC): 000FK9XR6 Budget (BOC): 2532 Cost:				
	26A6A DCN - Line ID: 192660E071-001				
	Funding Flag: Partial				
	Funded: -\$1,101,928.51				
	Accounting Info:				
	18-19-C-2660000-000FK9XR6-2532-26A6A-192660E071-00				
	2 BFY: 18 EFY: 19 Fund: C Budget Org: 2660000				
	Program (PRC): 000FK9XR6 Budget (BOC): 2532 Cost:				
	26A6A DCN - Line ID: 192660E071-002				
	Funding Flag: Partial				
	Funded: -\$85,644.49				
2N 75 40 04 45	1	1			